Patent claims

1. Method for immunostimulation in a mammal, comprising the following steps:
   a. administration of at least one mRNA containing a region which codes for at least one antigen of a pathogen or at least one tumour antigen and
   b. administration of at least one component of at least one of the following categories chosen from the group consisting of a cytokine, a cytokine mRNA, an adjuvo-viral mRNA, a CpG DNA and an adjuvant RNA.

2. Method according to claim 1, wherein step b. is carried out 1 minute to 48 hours, preferably 20 minutes to 36 hours, equally preferably 30 minutes to 24 hours, more preferably 10 hours to 30 hours, most preferably 12 hours to 28 hours, especially preferably 20 hours to 26 hours after step a.

3. Method according to one of the preceding claims, wherein in step a. at least one RNase inhibitor, preferably RNasin or aurintricarboxylic acid, is additionally administered.

4. Method according to one of the preceding claims, wherein an immune response is intensified or modulated, preferably is modified from a Th2 immune response into a Th1 immune response.

5. Method according to one of the preceding claims, wherein the at least one mRNA from step (a.) contains a region

which codes for at least one antigen from a tumour chosen from the group consisting of 707-AP, AFP, ART-4, BAGE, β-catenine/m, Bcr-abl, CAMEL, CAP-1, CASP-8, CDC27/m, CDK4/m, CEA, CMV pp65, CT, Cyp-B, DAM, EGFRI, ELF2M, ETV6-AML1, G250, GAGE, GnT-V, Gp100, HAGE, HBS, HER-2/neu, HLA-A*0201-R170I, HPV-E7, HSP70-2M, HAST-2, hTERT (or hTRT), influenza matrix protein, in particular influenza A matrix M1 protein or influenza B matrix M1 protein, iCE, KIAA0205, LAGE, e.g. LAGE-1, LDLR/FUT, MAGE, e.g. MAGE-A, MAGE-B, MAGE-C, MAGE-A1, MAGE-2, MAGE-3, MAGE-6, MAGE-10, MART-1/melan-A, MC1R, myosine/m, MUC1, MUM-1, -2, -3, NA88-A, NY-ESO-1, p190 minor bcr-abl, Pml/RARα, PRAME, proteinase 3, PSA, PSM, PTPRZ1, RAGE, RU1 or RU2, SAGE, SART-1 or SART-3, SEC61G, SOX9, SPC1, SSX, survivin, TEL/AML1, TERT, TNC, TPI/m, TRP-1, TRP-2, TRP-2/INT2, tyrosinase and WT1.

6. Method according to one of the preceding claims, wherein the at least one cytokine is chosen from the group consisting of IL-1 (α/β), IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-12, IL-13, IL-15, IL-18, IL-21, IL-22, IL-23, IFN-α, IFN-β, IFN-γ, LT-α, MCAF, RANTES, TGFα, TGFβ1, TGFβ2, TNFα, TNFβ and particularly preferably G-CSF or GM-CSF or M-CSF.

7. Method according to one of the preceding claims, wherein the at least one mRNA from step (a.) and/or from step (b.) is in the form of naked or complexed mRNA.

8. Method according to one of the preceding claims, wherein the at least one mRNA from step (a.) and/or from step (b.) is in the form of globin UTR (untranslated regions)-stabilized mRNA, in particular β-globin UTR-stabilized mRNA.

9. Method according to one of the preceding claims, wherein the at least one mRNA from step (a.) and/or from step (b.) is in the form of modified mRNA, in particular stabilized mRNA.

10. Method according to one of the preceding claims, wherein the G/C content of the coding region of the modified mRNA from step (a.) and/or from step (b.) is increased compared with the G/C content of the coding region of the wild-type RNA, the coded amino acid sequence of the modified mRNA preferably not being modified compared with the coded amino acid sequence of the wild-type mRNA.

11. Method according to one of the preceding claims, wherein the A/U content in the environment of the ribosome binding site of the modified mRNA from step (a.) and/or from step (b.) is increased compared with the A/U content in the environment of the ribosome binding site of the wild-type mRNA.

12. Method according to one of the preceding claims, wherein the coding region and/or the 5' and/or 3' untranslated region of the modified mRNA from step (a.) and/or from step (b.) is modified compared with the wild-type mRNA

such that it contains no destabilizing sequence elements, the coded amino acid sequence of the modified mRNA preferably not being modified compared with the wild-type mRNA.

13. Method according to one of the preceding claims, wherein the modified mRNA from step (a.) and/or from step (b.) has a 5' cap structure and/or a poly(A) tail, preferably of at least 25 nucleotides, more preferably of at least 50 nucleotides, even more preferably of at least 70 nucleotides, equally more preferably of at least 100 nucleotides, most preferably of at least 200 nucleotides, and/or at least one IRES and/or at least one 5' and/or 3' stabilizing sequence.

14. Method according to one of the preceding claims, wherein the modified mRNA from step (a.) and/or from step (b.) or the adjuvant RNA from step (b.) contains at least one analogue of naturally occurring nucleotides.

15. Method according to one of the preceding claims, wherein the modified mRNA from step (a.) and/or from step (b.) or the adjuvant RNA from step (b.) is complexed or condensed with at least one cationic or polycationic agent.

16. Method according to one of the preceding claims, wherein the cationic or polycationic agent is chosen from the group consisting of protamine, poly-L-lysine, poly-L-arginine and histones.

17. Method according to one of the preceding claims for treatment of tumour diseases, allergies, autoimmune diseases, such as multiple sclerosis, and protozoological, viral and/or bacterial infections.

18. Product comprising at least one mRNA containing a region which codes for at least one antigen of a pathogen or at least one tumour antigen, and at least one component from at least one of the following categories chosen from the group consisting of a cytokine, a CpG DNA, a cytokine mRNA, an adjuvo-viral mRNA and an adjuvant RNA, as a combination preparation for simultaneous, separate or time-staggered use in the treatment and/or prophylaxis of tumour diseases, allergies, autoimmune diseases, such as multiple sclerosis, and viral and/or bacterial infections.

19. Kit comprising at least one mRNA containing a region which codes for at least one antigen of a pathogen or at least one tumour antigen, and at least one component of at least one category chosen from the group consisting of a cytokine, a cytokine mRNA, an adjuvo-viral mRNA, a CpG DNA and an adjuvant RNA, the at least one mRNA containing a region which codes for at least one antigen of a pathogen or at least one tumour antigen, and the at least one cytokine or the at least one cytokine mRNA or the at least one CpG DNA or the at least one adjuvant RNA or the at least one adjuvo-viral mRNA being separate from one another.

20. Use of the kit according to claim 19 for treatment and/or prophylaxis of tumour diseases, allergies, autoimmune diseases, such as multiple sclerosis, and protozoological, viral and/or bacterial infections.